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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,245	02/18/2004	Jaime Romero	OS 457.002	5228

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,245	ROMERO, JAIME	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47 and 49-69* is/are pending in the application.

4a) Of the above claim(s) *1-22,26,30,46,49,50 and 52-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25, 27-29, 31-45, 47, 51, 68, and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicant's amendment and remarks, which were filed on 2 April 2008.
- The 35 USC 112, 2nd paragraph rejection of the previous Office action is withdrawn in view of the amendment.

* * * * *

Response to Amendment

The declaration under 37 CFR 1.132 filed on 27 November 2007 is insufficient to overcome the rejection of claims 23-25, 27-29, 31-45, 47, 51, 68 and 69 based upon Skinner, in view of Miller, further in view of Cristofori as set forth in the last Office action because it refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Furthermore, the declaration states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. For further explanation, see "response to arguments" section, below.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-25, 27-29, 31-45, 47, 51, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner (U.S. Patent No. 6,210,710) in view of Miller (U.S. Application No. 20050008690), further in view of Cristofori et al. (U.S. Patent No. 5,252,339).

Skinner teaches a timed (sustained) release nutritional supplement (*see* col. 2, lines 8-22). The disclosed composition is comprised of:

- the water-soluble nutritional supplement (ascorbic acid) of instant claims 23-25 (*see* col. 3, line 58);
- the saccharide (lactose) of instant claims 23-25 and 32-35 (*see* col. 4, line 49);
- the excipient (calcium phosphate) of instant claims 23-25 (*see* col. 4, lines 48-49);
- the lubricant (magnesium stearate) of instant claims 23-25 (*see* col. 4, line 59);
- the agglutinative (hydroxyethylcellulose) of instant claims 23-25 (*see* col. 2, line 66); and
- the plasticizer (stearic acid) of instant claims 23-25 (*see* col. 4, line 58);
- the core and coating of instant claim 28 (*see* col. 5, lines 9-26);

Skinner explains that the disclosed composition is beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets (*see* col. 1, lines 48-56).

While Skinner does not explicitly teach all the instant claimed percentages, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

Skinner teaches that release profiles may be adjusted as desired (*see* col. 5, lines 15-26). Thus, the release profile of instant claims 23 and 51 may be determined by a person of ordinary skill in the art based on routine experimentation.

Skinner does not disclose the capsule of instant claim 29, the silicon dioxide of instant claim 37, the talc of instant claim 39, the HPMC of instant claim 41, the Shellac of instant claim 43, the chondroitin of instant claim 47, or the glucosamine sulfate of instant claim 68.

Miller teaches a capsule formulation (*see* abstract) comprising:

- the silicon dioxide of instant claim 37 (*see* example 13);
- the talc of instant claim 39 (*see* paragraph 0090);
- the HPMC of instant claim 41 (*see* paragraph 0060);
- the Shellac of instant claim 43 (*see* example 13);
- the chondroitin of instant claim 47 (*see* example 1); and
- the glucosamine sulfate of instant claim 68 (*see* example 1).

Skinner does not disclose the diethylphthalate of instant claim 45. However, use of diethylphthalate as a plasticizer is well known in the art, as shown by Cristofori (*see* col. 5, line 2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose water-soluble nutritional supplement in a timed release formulation comprising a saccharide, an excipient, a lubricant, an agglutinative, and a plasticizer, as taught by Skinner. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides flexibility in release profiles that are stable and economical for compressed tablets, as explained by Skinner.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-25, 27-29, 31-45, 47, 51, 68 and 69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/910,787 ('787). Although the conflicting claims are not identical, they are not patentably distinct from each other because '787 claims a timed release composition comprising a saccharide, an excipient, a lubricant, an agglutinative, and a plasticizer. *See* claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicant's arguments regarding the 35 USC 103 rejection filed on 27 November 2007 have been fully considered but they are not persuasive.

1. Applicant argues that "formulation considerations relating to compressed tablets and coated pellets are very different." See remarks, page 30.

Examiner respectfully submits that "compressed tablet" reads on the "pellet" when the latter term is given its broadest reasonable interpretation. Applicant provides not special definition of the term "pellet" in the specification. Furthermore, applicant claims one pellet or more than one pellets. A dosage form comprising one pellet may reasonably be interpreted as a compressed tablet. Finally, applicants do not specify how the pellet is formed; based on standard practice in the art, it would be reasonable to assume that the pellet is formed by direct compression.

Thus, it is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. *See* MPEP § 2111 and 2123.

2. Applicant argues that the claimed formulation has unexpected results. See remarks, page 31.

Examiner respectfully submits that applicant does not specify what those unexpected results are. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2145.

3. Applicants argue that there is no suggestion to combine the prior art references. See remarks, pages 31-32.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art references all relate to the same field of endeavor as the instant application, i.e. controlled release oral dosage forms. As explained above, no special definition of the term "pellet" is provided. Thus, the formulations of the prior art read on the instant application, as claimed.

4. Applicant argues that the "finite number of identified, predictable solutions" test of the KSR International v. Teleflex Inc. opinion was not met. *See* remarks, page 32.

Examiner respectfully submits that the prior art recites a delimited number of active ingredients and excipients in controlled release formulations. Included amount the recited active ingredients and excipients are those instantly claimed. Since the prior art discloses same ingredients as instantly claimed in the same formulation as instantly claimed, examiner respectfully submits that the solutions provided by the cited prior art are finite and predictable.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618